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Federal Health Insurance for the Aged

Proposed Conditions for Coverage of Services of Independent Laboratories

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social Security Administration

[20 CFR Part 405]

[Regs. 5]

FEDERAL HEALTH INSURANCE FOR THE AGED

Proposed Conditions for Coverage of Services of Independent Laboratories

Notice is hereby given, pursuant to the Administrative Procedure Act (5 U.S.C. 553) that the amendments to the regulations set forth in tentative form below are proposed by the Commissioner of Social Security, with the approval of the Secretary of Health, Education, and Welfare. For an independent laboratory to qualify for reimbursement under the supplementary medical insurance part of the health insurance program for the aged, the independent laboratory must meet certain statutory requirements of section 1861(s) of the Social Security Act and conditions established by regulations in the interest of health and safety. The proposed amendments to the regulations clarify and expand the conditions by providing:

(1) Procedures for recertification of laboratories whose coverage has been withdrawn or whose specialty approval has been revoked on the basis of unsatisfactory performance in proficiency testing;

(2) Additional reasons for finding a laboratory not in compliance, or no longer in compliance, with the requirements;

(3) One particular section for definitions of terms;

(4) An indefinite extension of the time during which individuals meeting alternative requirements may continue to qualify as directors under Medicare;

(5) Consistency between Medicare regulations and those promulgated by the Center for Disease Control under the Clinical Laboratories Improvement Act of 1967 (Public Law 90–174, section 353) for laboratories engaged in interstate commerce;

(6) An additional requirement that all laboratories successfully participate in an acceptable proficiency testing program;

(7) A modification permitting routine and repetitive tests in clinical laboratories to be performed by a technician trainee provided that there is direct supervision by qualified personnel; and

(8) Greater emphasis on internal quality control by making it a condition for coverage of services of independent laboratories rather than a factor of laboratory management.

Prior to the final adoption of the proposed amendments, consideration will be given to any data, comments, or arguments pertaining thereto which are submitted in writing in triplicate to the Commissioner of Social Security, Department of Health, Education, and Welfare Building, Fourth and Independence Avenue SW., Washington, DC 20201, within a period of 30 days from the date of publication of this notice in the FEDERAL REGISTER.

Written documents received in response to this notice will be available for public inspection during regular business hours at the Washington Inquiries Section, Office of Public Affairs, Social Security Administration, Department of Health, Education, and Welfare, North Building, Room 3193, 330 Independence Avenue SW., Washington, DC 20201.

The proposed regulations are to be issued under the authority contained in sections 1102, 1861(s), 1863, 1864, and 1871, 49 Stat. 647, as amended, 79 Stat. 314–316, 79 Stat. 320, 79 Stat. 325–326, 79 Stat. 331, 42 U.S.C. 1302, 1395 et seq.

Dated: December 27, 1971.

ROBERT M. BALL,
Commissioner of Social Security.

Approved: February 8, 1972.

ELLIOT L. RICHARDSON,
Secretary of Health, Education, and Welfare.

Subpart M of Part 405 of Chapter III of Title 20 of the Code of Federal Regulations is revised to read as follows:

Subpart M—Conditions for Coverage of Services of Independent Laboratories

§ 405.1301 Conditions for coverage of services of independent laboratories; general.

(a) *Introduction.* The conditions for coverage of services of independent laboratories and related policies set forth in this Subpart M, state the specific requirements that must be met by an independent laboratory in order for its services to qualify for reimbursement under the supplementary medical insurance part of the Health Insurance for the Aged Program. The services of a qualified independent laboratory for which reimbursement may be made under the supplementary medical insurance program relate only to diagnostic tests performed in an independent laboratory as defined in § 405.1311(a). Diagnostic laboratory tests, for purposes of section 1861(s) (10) and (11) of the Act and for purposes of this Subpart M, shall include only those clinical and anatomical pathology diagnostic tests and procedures defined in § 405.1311(b). Diagnostic tests furnished by out-of-hospital physicians whose primary practice is directly attending patients and/or consultation as defined in § 405.1311(f), even though conducted partly through diagnostic procedures, are considered physicians' services rather than clinical laboratory services. As such, the office in which these services are provided is exempt from these conditions.

(b) *General.* Section 1861(s) of the Act, which includes the provision for the coverage in the medical insurance program of diagnostic tests performed in an independent laboratory, provides that, as a condition for coverage of such tests, an independent laboratory, in any State in which State or local law provides for licensing laboratories, be licensed pursuant to such law or be approved by the agency of the State or locality responsible for such licensure as meeting the standards established for licensing. As a further condition, the statute requires that the independent laboratory meet such standards as the Secretary finds necessary to assure the health and safety of individuals with respect to whom these tests are performed.

(c) *State agency certification.* The law makes provision for the designation of State health agencies, or other State agencies, to assist the Secretary in determining whether there is compliance with the conditions for coverage of services of independent laboratories. The designated State agencies will certify to the Secretary those laboratories which they find meet the conditions and the specialties and subspecialties for which the laboratory is recommended for certification. Services provided in a laboratory that is determined by the Secretary to be in substantial compliance with the conditions relating to health and safety and which meet the statutory licensure requirement are reimbursable under the medical insurance program.

(d) *Certifications and determinations.* Certifications and determinations as to whether an independent laboratory is in substantial compliance with the conditions are made upon the filing by the laboratory of an application on a form prescribed by the Secretary.

§ 405.1302 Conditions for coverage of services; general.

Services of an independent laboratory are reimbursable under the program only if the laboratory meets the statutory requirement of section 1861(s)(10) of the Act and the Secretary has determined that the laboratory is in substantial compliance with all the other conditions set forth in this Subpart M. These additional conditions (established in the interest of health and safety) are essential to the maintenance of quality of care and the adequacy of the services and facilities which the laboratory provides. Variation in the type and size of laboratories and the nature and scope of services offered will be reflected in differences in the details of organization, staffing, and facilities. However, the test is whether there is substantial compliance with each of the conditions.

§ 405.1303 Standards; general.

A series of standards, almost all interpreted by explanatory factors, is set forth in this Subpart M with respect to each condition for coverage of services. Reference to these standards will enable the State agency surveying a facility to document the activities of the laboratory, to determine the appropriate laboratory specialties or subspecialties set out in § 405.1314(b) for which the laboratory is qualified to receive reimbursement under the Supplementary Medical Insurance Benefits part of the Health Insurance for the Aged program, to establish the nature and extent of its deficiencies, if any,

and to assess the facility's need for improvement in relation to the prescribed condition. In substance, the application of the standards, together with the explanatory factors, will indicate the extent and degree to which an independent laboratory is complying with each condition.

§ 405.1304 State agencies.

As provided by title XVIII of the Social Security Act, State agencies, operating under agreements with the Secretary, are used in determining whether independent laboratories meet the conditions. Pursuant to such an agreement, a State agency certifies to the Secretary findings as to whether independent laboratories are in substantial compliance with the conditions. Such certifications include findings as to whether each of the conditions is substantially met for those specialties or subspecialties in which the laboratory performs tests or has the capability to perform such tests as defined in § 405.1314. The Secretary, on the basis of such certification from the State agency, determines whether or not the level of facilities and services of the laboratory represent the required achievements of substantial compliance with the conditions and transmits to the laboratory a written notice of the determination.

§ 405.1305 Substantial compliance—Principles for evaluation.

(a) Independent laboratories are considered in substantial compliance with the conditions for coverage of their services upon acceptance by the Secretary of findings, adequately documented and certified to by the State agency, showing that:

(1) The laboratory meets the specific statutory requirement of section 1861(s)(10) of the Act and is found to be operating in accordance with all the conditions with no significant deficiencies; or

(2) The laboratory meets the specific statutory requirement of section 1861(s)(10) of the Act but is found to have deficiencies with respect to one or more conditions, but

(i) It is making reasonable plans and efforts to correct the deficiencies, and as evidence of such plans and efforts to correct, provides for each deficiency a written plan of and schedule for correction, and

(ii) Notwithstanding the deficiencies it is rendering adequate service without hazard to the health or safety of individuals being served, taking into account special procedures or precautionary measures which have been or are being instituted; or

(3) The laboratory meets the specific statutory requirement of section 1861(s)(10) of the Act but is found to have deficiencies with respect to one or more conditions, but

(i) Successfully participates in such quality assurance procedures (see § 405.1314) by which it demonstrates acceptable and proficient performance, and

(ii) Notwithstanding the deficiencies it is rendering adequate service without hazard to the health and safety of individuals being served.

(b) Independent laboratories previously found in substantial compliance, but which have had their approval revoked in total or in a specialty or subspecialty because of unsatisfactory performance in proficiency testing, may subsequently be certified by the State agency and determined by the Secretary to be in substantial compliance with the conditions where:

(1) The laboratory is in substantial compliance under the provisions of paragraph (a) of this section, and

(2) (i) After a 6-month period, an appraisal of the laboratory's performance in a proficiency testing program as defined in § 405.1311(c) reflects satisfactory test results on at least two sets of specimens, or

(ii) After a 3-month period, the State agency's assessment of the laboratory's performance in examining proficiency test samples, analyzed during at least two State agency onsite visits, establishes the laboratory's competency.

§ 405.1306 Time limitations on certification of substantial compliance.

(a) All initial certifications by the State agency that an independent laboratory is in substantial compliance with the conditions will be effective for a period of 1 year, beginning with July 1, 1966, or, if later, with the date on which the laboratory is first found to be in substantial compliance with the conditions. The Secretary's determination that the laboratory is in substantial compliance with the conditions remains in effect until such time as notice of revision or withdrawal of approval is given. State agencies may visit or resurvey laboratories where necessary to ascertain continued compliance or to accommodate to periodic or cyclical survey programs. A State may, at any time, find and certify to the Secretary that a laboratory is no longer in compliance.

(b) If a laboratory is certified by the State agency and determined by the Secretary to be in substantial compliance under the provisions of § 405.1305(a), the following information will be incorporated into the finding and into the notice to the laboratory of the determination of coverage of its services under the medical insurance program:

(1) A statement of the deficiencies which were found, and

(2) A description of progress which has been made and further action which is being taken to remove the deficiencies, and

(3) A scheduled time for a resurvey of the laboratory to be conducted not later than the 12th month (or earlier, depending on the nature of the deficiencies) of the period of certification.

§ 405.1307 Certification of noncompliance.

(a) The State agency will certify that the entire laboratory is not in compliance with the conditions or, where a determination of compliance has been made, that a laboratory is no longer in compliance where:

(1) The laboratory is not in compliance with the statutory requirement of section 1861(s)(10) of the Act; or

(2) The laboratory has deficiencies of such character as to seriously limit the capacity of the laboratory to render adequate service or as to place health and safety of individuals in jeopardy, and the State agency concludes after discussion with the laboratory that there is no early prospect of such significant improvement as to establish substantial compliance; or

(3) After a previous period or part thereof for which the laboratory was certified with a finding of significant deficiencies, there is a lack of progress toward a removal of deficiencies which the State agency finds are adverse to the health and safety of individuals being served; or

(4) The laboratory demonstrates unsatisfactory performance in a proficiency testing program as described in § 405.1314 in all specialties or subspecialties for which it is approved to perform tests; or

(5) The laboratory refuses to participate in proficiency testing programs as described in § 405.1314 in all specialties or subspecialties for which it is requesting approval; or

(6) The laboratory has significant deficiencies with respect to one or more conditions and fails to demonstrate satisfactory performance in the quality assurance procedures as established by the Secretary under the provisions of § 405.1305(a)(3); or

(7) The laboratory refuses to permit a designated State agency to conduct an onsite visit or resurvey; or

(8) The laboratory fails to give notice of any change in ownership within 30 days of such change; or

(9) The laboratory fails to give notice of any change in directors or supervisors within 30 days of the date of such change.

(b) After a previous period or part thereof in which a laboratory was certified, the State agency will certify that certain specialties or subspecialties are no longer approved when the State agency finds that the laboratory has deficiencies including those enumerated in factors in subparagraphs (3), (4), (5), (6), and (7) of paragraph (a) of this section in those specialties and subspecialties of such magnitude as to significantly affect its competency.

§ 405.1308 State agency findings for determining substantial compliance.

Findings made by a State agency as to whether an independent laboratory is in substantial compliance with the conditions require a thorough evaluation of the laboratory. The State evaluation will take into consideration:

(a) The degree to which each standard, as well as the total set of standards relating to a condition, is met;

(b) When there is a deficiency, whether the deficiency creates a serious hazard to health and safety; and

(c) Whether the laboratory is making reasonable plans and efforts to correct the deficiency within a reasonable period.

Exception. Notwithstanding the rules for determining substantial compliance set forth in this section, a finding of substantial compliance shall not be applicable with respect to the education and experience qualification requirements for laboratory personnel prescribed in this Subpart M. The education and experience qualification requirements for laboratory personnel must be met in all respects. However, technical personnel not meeting the training and experience requirements defined in this Subpart M but who successfully participate in proficiency and/or equivalency examinations when these examinations are available and approved by the Secretary will be deemed to meet these requirements.

§ 405.1309 Conditions—Documentation of findings.

The findings of the State agency with respect to each of the conditions shall be adequately documented. To evaluate such findings, information regarding scope and volume of services provided in those specialties in which the laboratory is requesting certification shall be obtained, where appropriate. Where the State agency certifies to the Secretary that a laboratory is not in compliance with the conditions, the documentation shall include a report of any discussions with the staff of the laboratory concerning the deficiencies, a report of the laboratory's responses with respect to such discussions, and the State agency's assessment of the prospects for such improvements as to enable the laboratory to achieve substantial compliance with the conditions.

§ 405.1310 Conditions—Compliance with State and local laws.

The laboratory shall conform with all applicable State and local laws.

(a) *Standard; licensure.* Any laboratory located in any State in which State or applicable local law provides for the licensing of laboratories is (1) licensed pursuant to such law, or (2) approved, by the agency of the State or locality responsible for licensing laboratories, as meeting the standards established for such licensing.

(b) *Standard; licensed staff.* The director and the staff of the laboratory are licensed or registered in accordance with applicable laws.

(c) *Standard; fire and safety.* The laboratory is in conformity with laws relating to fire and safety, and to other relevant matters.

§ 405.1311 Definitions.

(a) *Independent laboratory.* An independent laboratory performing diagnostic tests is one which is independent both of the attending or consulting physician's office and of a hospital which meets at least the requirements specified in section 1861(e) of the Act to qualify for payment for emergency hospital services under section 1814(d) of the Act. A laboratory which: (1) Is located in a hospital which meets at least the requirements specified in section 1861(e) of the Act to qualify for payment for emergency hospital services under section 1814(d) of the Act or, if outside the hospital, is operated under the supervision of the hospital or its organized medical staff and (2) serves the hospital's patients, is not an independent laboratory. Services furnished by out-of-hospital laboratories under the direction of a physician, such as a pathologist, are considered to be subject to the conditions where the physician holds himself and the facilities of his office out to other physicians as being available for the performance of diagnostic tests. A laboratory maintained by a physician for performing diagnostic tests primarily for his own patients is exempt from the conditions, even though such laboratory does diagnostic tests on referral from other physicians.

(b) *Clinical laboratory tests.* A clinical laboratory test is a microbiological, serological, chemical, hematological, radiobioassay, cytological, biophysical, immunohematological or other pathological examination which is performed on materials derived from the human body, to provide information for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition.

(c) *Proficiency testing program.* A proficiency testing program is one which (1) is either operated or approved by the State agency, or approved by the Secretary, and (2) meets at a minimum the requirements for a proficiency testing program as outlined by the Secretary.

(d) *Subsequent to graduation.* As used in §§ 405.1312 and 405.1313 the phrase "subsequent to graduation" refers to laboratory training and experience acquired after successful completion of the degree referred to in those sections. However, if the experience is gained prior to acquiring such degree, the length of experience required would be calculated on an equivalency basis of 1.5 years of predegree training and experience for every 1 year of postdegree training and experience. Furthermore, when part of the experience must be in one of the laboratory specialities, experience in the specialty must comprise at least half of the total required. However, with regard to § 405.1314, the required experience and training must be obtained after the acquisition of the lowest educational degree specified.

(e) *Director at the doctoral level.* As used throughout §§ 405.1312 and 405.1313 the term "director at the doctoral level" refers only to persons having the qualifications described in § 405.1312(b) (1), (2), (3), and (5) (i).

(f) *Consultation.* A "consultation" is a deliberation of two or more physicians with respect to the diagnosis or treatment in any particular case. Consultation, as distinguished from providing clinical laboratory services, includes history taking, examination of the patient, and transmitting to the attending physician an opinion concerning diagnosis and/or treatment.

(g) *Technician trainee.* A "technician trainee" is a high school graduate or equivalent who has not had the required 2 years of clinical laboratory experience to qualify as a technician.

(h) *Personal and direct supervision.* The phrase "personal and direct supervision" requires that a qualified supervisor technologist, or cytotechnologist be present at least in the immediate bench area when laboratory procedures are being performed in order to carry out those specific tasks which are evidence of his constant involvement in and supervision over the performance of the procedures.

(i) *Group practice.* The term "group practice" means an organized, cooperative practice between physicians representing different specialized fields of medicine, who share facilities, space, and responsibilty of patient care and who provide a substantially complete array of the services which might be necessary for the care of a patient's health.

(j) *Accredited.* As used in these regulations, the term "accredited" refers to the approval conferred upon schools, institutions, or programs where appropriate by a nationally recognized accrediting agency or association as determined by the U.S. Commissioner of Education.

§ 405.1312 Condition—Clinical laboratory; laboratory director.

The clinical laboratory is under the direction of a qualified person.

(a) *Standard; administration.* The laboratory has a director who administers the technical and scientific operation of the laboratory including the reporting of findings of laboratory tests. The factors explaining the standard are as follows:

(1) The director serves the laboratory full time, or on a regular part-time basis. If he serves on a regular part-time basis, (i) he does not individually serve as director of more than three laboratories (hospital or independent) or, (ii) he provides an associate, qualified under the standard in paragraph (b) of this section to serve as assistant director in each laboratory. Such assistant director does not serve more than three laboratories.

(2) Commensurate with the laboratory workload, the director spends an adequate amount of time in the laboratory to direct and supervise the technical performance of the staff and is readily available for personal or telephone consultation.

(3) The director is responsible for the proper performance of all tests made in the laboratory.

(4) The director is responsible for the employment of qualified laboratory personnel and their inservice training.

(5) If the director is to be continuously absent for more than 1 month, arrangements are made for a qualified substitute director.

(b) *Standard; laboratory director—qualification.* The laboratory director meets one of the following requirements:

(1) He is a physician certified in anatomical and/or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for such certification (board eligible).

(2) He is a physician who (i) is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the labora-

tory specialties, or (ii) is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, or other national accrediting board in one of the laboratory specialties, or (iii) is certified by the American Society of Cytology to practice cytopathology, or possesses qualifications which are equivalent to those required for such certification, or (iv) subsequent to graduation as defined in § 405.1311(d) has had 4 or more years of general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level as defined in § 405.1311(e)—of a hospital, a health department, university, or medical research institution, in a laboratory approved under the supplementary medical insurance benefits program, or in a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.

(3) He is a dentist who is certified by the American Board of Oral Pathology or possesses qualifications which are equivalent to those required for certification (board eligible).

(4) He holds an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as his major subject and (i) is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, or other national accrediting board acceptable to the Secretary in one of the laboratory specialties, or (ii) subsequent to graduation as defined in § 405.1311(d), has had 4 or more years of general clinical laboratory training and experience, of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level as defined in § 405.1311(e)—of a hospital, a health department, university, or medical research institution, in a laboratory approved under the supplementary medical insurance benefits program, or in a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.

(5) He is a bioanalyst, accredited in bioanalysis by the American Board of Bioanalysis, or possesses qualifications which are equivalent to those for such accreditation (board eligible).

(6) If he first applied for certification of a laboratory as its director prior to July 1, 1971, he was responsible for the direction of a clinical laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, meets one of the following requirements:

(i) He is a physician and subsequent to graduation as defined is § 405.1311(d) has had at least 4 years of pertinent clinical experience;

(ii) He holds a master's degree from an accredited institution with a chemical, physical, or biological science as his major subject and subsequent to graduation has had at least 4 years of pertinent clinical laboratory experience;

(iii) He holds a bachelor's degree from an accredited institution with a chemical, physical, or biological science as his major subject and subsequent to graduation has had at least 6 years of pertinent clinical laboratory experience, or

(iv) He has achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970.

§ 405.1313 Condition—Clinical laboratory; supervision.

The clinical laboratory is supervised by qualified personnel.

(a) *Standard; supervision.* The laboratory has one or more supervisors who, under the general direction of the laboratory director, supervise technical personnel and reporting of findings, perform tests requiring special scientific skills, and, in the absence of the director, are held responsible for the proper performance of all laboratory procedures. A laboratory director who qualifies under § 405.1312(b) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor. The factors explaining the standard are as follows:

(1) There are two categories of required supervisors. A general supervisor—one who meets the requirements of paragraph (b) of this section—is on the laboratory premises during all hours in which tests are being performed. A technical supervisor—one who meets the pertinent requirements of § 405.1314(b)—spends an adequate amount of time in the laboratory to supervise the technical performance of the staff in his specialty and is readily available for personal or telephone consultation. A general supervisor may also be a technical supervisor in those specialties in which he meets the requirements of § 405.1314(b). A supervisor is not required to be on the premises during the performance of procedures received for emergency purposes; provided that the person performing tests is qualified to perform such tests and the supervisor, who is responsible for the results of his work reviews them during his next duty period, and a record is maintained to reflect the actual review.

(b) *Standard; supervisor—qualification.* The laboratory supervisor meets one of the following requirements:

(1) He (i) is a physician or has earned a doctoral degree from an accredited institution with a chemical, physical, or biological science as his major subject, and (ii) subsequent to graduation as defined in § 405.1311(d) has had at least 2 years' experience in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level as defined in § 405.1311(e)—of a hospital, a health department, university or medical research institution; or in a laboratory approved under the supplementary medical insurance benefits program; or in a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State;

(2) He holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and subsequent to graduation as defined in § 405.1311(d) has had at least 4 years of pertinent laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in a clinical laboratory—with a director at the doctoral level as defined in § 405.1311(e)—of a hospital, a health department, university, or medical research institution, or in a laboratory approved under the supplementary medical insurance benefits program, or in a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State;

(3) He is qualified as a clinical laboratory technologist pursuant to the provisions of § 405.1315(b) (1), (2), (3), or (4), and has had at least 6 years of pertinent laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in a clinical laboratory—with a director at the doctoral level as defined in § 405.1311(e)—of a hospital, university, health department, or medical research institution; or in a laboratory approved under the supplementary medical insurance benefits program; or in a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State; or

(4) If he first qualified as a supervisor prior to July 1, 1971, he (i) has had at least 15 years of pertinent clinical laboratory experience prior to January 1, 1968: *Provided*, That a minimum of of 30 semester hours of credit toward a bachelor's degree with a chemical, physical, or biological science as his major subject or 30 semester hours in an approved school of medical technology shall reduce the required years of experience by 2 years, with any additional hours further reducing the required years of experience at the rate of 15 hours for 1 year; (ii) has performed the duties of a clinical laboratory supervisor at any time between July 1, 1961, and January 1, 1968; and (iii) has performed the duties of a supervisor for at least 2 years after July 1, 1966, or during the 15-year qualifying period specified in subdivision (i) of this subparagraph in a clinical laboratory—with a director at the doctoral level as defined in § 405.1311(e)—of a hospital, health department, university, or medical research institution; or in a laboratory approved under the supplementary medical insurance benefits program; or in a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.

§ 405.1314 Condition—Clinical laboratory; tests performed.

Subject to the provision that the requirements of this section apply only to those tests and procedures performed for individuals enrolled under the supplementary medical insurance benefits program (see Subpart B of this Part 405), the clinical laboratory performs only those laboratory tests and procedures that are within the specialties in which the laboratory director or super-

visors are qualified. If a laboratory has a qualified director or supervisor in a given specialty, based on such individual having met the educational and experience requirements of paragraph (b) of this section and the laboratory has the necessary equipment, space, facilities, and personnel to perform tests in that specialty and can show successful participation in the specialty in a proficiency testing program, certification of approval in the specialty or subspecialty may be given notwithstanding the fact that the laboratory is not actually performing tests in that specialty.

(a) *Standard; proficiency testing.* All laboratories must successfully participate in a proficiency testing program as defined in § 405.1311(c) covering all clinical and anatomical laboratory specialties and subspecialties as made available in which the laboratory is approved to perform tests for individuals enrolled under the supplementary medical insurance benefits program (see Subpart B of this Part 405). Laboratories shall receive and examine and/or analyze specimens delivered by mail or messenger at such times as designated by the proficiency testing service; shall maintain records of all proficiency testing results in programs in which it is a participant and make such records, including results and interpretations, available to the Secretary upon request. Results reflecting unsatisfactory performance in an acceptable proficiency testing program constitutes a basis for revoking approval or limiting the laboratory in specialties or subspecialties it may perform. An exception to this requirement may be made where such programs as determined by the State are not readily available or are not open for enrollment at the time these regulations are published, or at the time a laboratory first applies for coverage under Subpart M of this program. For laboratories currently certified under these conditions for coverage of services at the time of publication of these regulations, this exception shall be in effect only until such programs become available or are open for enrollment, but in no event, beyond 1 year following publication of these regulations. For laboratories subsequently applying for certification, the exemption shall be in effect until such programs become available or are open for enrollment, but in no event beyond 1 year following receipt by the laboratory of its certification approval.

(b) *Standard; procedures and tests—competency.* The laboratory performs only those laboratory procedures and tests that are within the specialties or subspecialties in which the laboratory director or supervisors are qualified. The factors explaining the standards are as follows:

(1) If the laboratory director or supervisor is a physician certified in both anatomical and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for certification (board eligible), the laboratory may perform anatomical and clinical laboratory procedures and tests in all specialties.

(2) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of microbiology, including the subspecialties of bacteriology, virology, mycology, and parasitology, the director or a supervisor, as defined previously, (i) holds an earned doctoral or master's degree in microbiology from an accredited institution or is a physician and (ii) subsequent to graduation as defined in § 405.1311(d) has had at least 4 years' experience in clinical microbiology.

(3) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of serology the director or a supervisor, as defined previously (i) holds an earned doctoral or master's degree in biology, chemistry, immunology, or microbiology from an accredited institution, or is a physician and (ii) subsequent to graduation as defined in § 405.1311(d) has had at least 4 years' experience in serology.

(4) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of hematology, including gross and microscopic examination of the blood, the director or a supervisor as defined previously, (i) holds a master's or a bachelor's degree in biology, immunology, or microbiology from an accredited institution and (ii) subsequent to graduation as defined in § 405.1311(d) has had at least 4 years' experience in hematology.

(5) If the factor in subparagraph (1) of this paragraph is not met and (i) the laboratory performs tests in the specialty of immunohematology, the director or a supervisor, as defined previously, is a physician with at least 2 years' experience in clinical hematology subsequent to graduation as defined in § 405.1311(d), or (ii) within the specialty of immunohematology, the laboratory performs tests in the subspecialties of blood grouping and Rh typing only, the director or a supervisor, as defined previously, holds a master's or bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation as defined in § 405.1311(d) has had at least 4 years' experience in immunohematology.

(6) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of clinical chemistry, the director or a supervisor, as defined previously, (i) holds an earned doctoral or master's degree in a chemical science or its equivalent from an accredited institution or is a physician, and (ii) subsequent to graduation as defined in § 405.1311(d) has had at least 4 years' experience in clinical chemistry.

(7) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of radiobioassay, the director or a supervisor, as defined previously (i) holds an earned doctoral, master's, or bachelor's degree in a chemical, physical, or biological science from an accredited institution or is a physician, and (ii) subsequent to graduation as defined in § 405.1311(d) has had at least 1 year of experience in radiobioassay.

(8) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of tissue pathology, the director or a supervisor, as defined previously is a physician who is certified in anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for certification (board eligible).

(9) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of diagnostic cytology, the director or a supervisor, as defined previously, (i) is a physician who is certified by the American Board of Pathology, or the American Osteopathic Board of Pathology, or possesses qualifications which are equivalent to those required for certification, or (ii) is a physician who is certified by the American Society of Cytology to practice cytopathology, or possesses qualifications which are equivalent to those required for certification (board eligible) (under this provision the laboratory is qualified to perform such tests only on that anatomic site for which he is certified); or (iii) is an individual who, pursuant to a request to establish his qualifications filed prior to January 1, 1971, has demonstrated competency (*a*) through at least 7 years of accumulative experience in a position of diagnostic responsibility in the field of clinical cytology or through 5 years of full-time training in diagnostic clinical cytology with suitable endorsement by a physician who has been his supervisor in such activity; (*b*) by the publishing of treatises, texts, or other publications on the subject of diagnostic cytology which are generally acknowledged and recognized by the medical profession as authoritative in the field; (*c*) by his appointment to and service in pertinent teaching and research positions in recognized schools of medicine; (*d*) by his acceptance into or award of membership and office in professional societies in this field; and (*e*) by his receipt of other professional honors for excellence in the use of procedures in exfoliative cytology for the diagnosis of a pathological condition (under this provision the laboratory is qualified to perform such tests only on that anatomic site with respect to which such competency is so established). The Social Security Administration, after documentation of the individual's qualifications by the State agency, will, with appropriate professional advice from the Public Health Service, make all determinations with respect to the requirements set forth in this subdivision (iii). An individual who qualifies under this subdivision (iii) is deemed also to meet the requirements of § 405.1312(b)(2)(ii).

(10) If the factor in subparagraph (1) or (8) of this paragraph is not met and the laboratory performs tests in oral pathology, the director or supervisor

is a dentist who is certified in oral pathology by the American Board of Oral Pathology or possesses qualifications which are equivalent to those required for certification (board eligible).

(11) A laboratory whose director qualifies under § 405.1312(b)(5) is qualified to perform tests in the laboratory specialties in which such director is qualified by training and experience, or in which he has achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service, as discussed in § 405.1312(b)(5). Under this provision the laboratory is qualified to perform tests in other specialties only if the supervisor meets the appropriate requirements of subparagraphs (1)–(10) of this paragraph. The laboratory he directs may perform tests in:

(i) Microbiology: If he has (*a*) a bachelor's degree in a science and subsequent to graduation has had at least 6 years of experience in microbiology; or (*b*) a master's degree in a biological science and 4 such years of experience.

(ii) Hematology: If he has (*a*) a bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 6 years of clinical laboratory experience of which at least 4 years' experience are in hematology; or (*b*) a master's degree in one of the above sciences and 4 years' experience in hematology.

(iii) Serology: If he has (*a*) a bachelor's degree in biology, chemistry, immunology, or microbiology and subsequent to graduation has had at least 6 years of experience in serology; or (*b*) a master's degree in one of the above sciences and 4 years' experience in serology.

(iv) Radiobioassay: If he has (*a*) a bachelor's degree in chemical, physical, or biological science and has had at least 6 years of clinical laboratory experience at least 1 year of which is in radiobioassay; or (*b*) a master's degree in one of the above sciences and 4 years of clinical laboratory experience at least 1 year of which is in radiobioassay.

(v) Blood grouping and Rh typing: If he has (*a*) a bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 6 years of clinical laboratory experience of which at least 4 years' experience are in hematology; or (*b*) a master's degree in one of the above sciences and 4 years' experience in hematology.

(vi) Clinical chemistry: If he has (*a*) a bachelor's degree in a chemical science or its equivalent and 6 years of experience in clinical chemistry; or, (*b*) a master's degree in a chemical science and 4 years' experience in clinical chemistry.

(vii) Any of the above specialties, if he has a bachelor's degree in medical technology and the designated experience in the specialty.

(12) A laboratory whose director qualifies under § 405.1312(b) (1), (2), (3), or (4) is qualified to perform tests in the laboratory specialties with respect to which such director or supervisor meets the pertinent requirements of subparagraphs (1) through (11) of this paragraph.

§ 405.1315 Condition—Clinical laboratory; technical personnel.

The clinical laboratory has a sufficient number of properly qualified technical personnel for the volume and diversity of tests performed.

(a) *Standard; technologist—duties.* The laboratory employs a sufficient number of clinical laboratory technologists to proficiently perform under general supervision the clinical laboratory tests which require the exercise of independent judgment. The factors explaining the standard are as follows:

(1) The clinical laboratory technologists perform tests requiring the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisors, only in those specialties or subspecialties in which they are qualified by education, training, and experience.

(2) With respect to specialties in which the clinical laboratory technologist is not qualified by education, training, or experience, he functions only under the direct supervision of the laboratory supervisor or other qualified technologist.

(3) Clinical laboratory technologists are in sufficient number to adequately supervise the work of technicians and trainees.

(4) An individual qualified as a cytotechnologist solely under paragraph (b)(6) of this section, may supervise technicians and trainees only in the specialty of cytology.

(b) *Standard; technologists—qualifications.* Each clinical laboratory technologist possesses a current license as a clinical laboratory technologist issued by the State, if such licensing exists, and meets one of the following requirements:

(1) Has earned a bachelor's degree in medical technology from an accredited college or university; or

(2) Has successfully completed 3 academic years of study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into, and has successfully completed a course of training of at least 12 months in, a school of medical technology approved by the Council on Medical Education of the American Medical Association; or

(3) Has earned a bachelor's degree in one of the chemical, physical, or biological sciences, and, in addition, at least 1 year of pertinent laboratory experience and/or training covering the specialty (ies) or subspecialty(ies) in which he performs tests; provided the combination has given him the equivalent in such specialty(ies) or subspecialty(ies) of the education and training described in subparagraph (1) or (2) of this paragraph; or

(4) Has successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with a distribution of courses as provided in subdivision (i) or (ii) of this subparagraph, and, in addition, has successfully completed experience and/or training covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him with education and training in medical technology equivalent to that described in subparagraph (1) and (2) of this paragraph. Distribution of course work: (Where semester hours are stated, it is understood that the equivalent in quarter hours is equally acceptable. The specified courses must have included lecture and laboratory work. Survey courses are not acceptable.)

(i) For those whose training was completed prior to September 15, 1963: At least 24 semester hours in chemistry and biology courses of which (*a*) not less than 9 semester hours must have been in chemistry and must have included at least 6 semester hours in inorganic chemistry, and (*b*) not less than 12 semester hours must have been in biology courses pertinent to the medical sciences.

(ii) For those whose training was completed after September 14, 1963: (*a*) 16 semester hours in chemistry courses which included at least 6 semester hours in inorganic chemistry and are creditable toward a major in chemistry; (*b*) 16 semester hours in biology courses which are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and (*c*) 3 semester hours of mathematics; or

(5) With respect to individuals first qualifying prior to July 1, 1971, an exception to the requirements in subparagraph (1), (2), (3), or (4) of this paragraph is made if (i) the technologist was performing the duties of a clinical laboratory technologist at any time between July 1, 1961, and January 1, 1968, and (ii) the technologist (*a*) has had at least 10 years of pertinent clinical laboratory experience prior to January 1, 1968 (a minimum of 30 semester hours of credit toward a bachelor's degree from an accredited institution with a chemical, physical, or a biological science as his major subject or 30 semester hours in an approved school of medical technology shall reduce the required years of experience by 2 years, with any additional hours further reducing the required years of experience at the rate of 15 hours for 1 year), and (*b*) has performed the duties of a clinical laboratory technologist for at least 2 years after July 1, 1966, or during the qualifying 10 years in a clinical laboratory—with a director at the doctoral level, as defined in § 405.1311 (e)—of a hospital, university, health department, or medical research institution; or in a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State; or in a laboratory approved under the supplementary medical insurance benefits program; or

(6) Each cytotechnologist shall possess a current license as a cytotechnologist issued by the State, if such licensing exists, and (i) shall have successfully completed 2 years in an accredited college or university with at least 12 semester hours in science, 8 hours of which are in biology, and (*a*) has had 12 months

of training in a school of cytotechnology approved by the Council on Medical Education of the American Medical Association or (*b*) has received 6 months' formal training in a school of cytotechnology approved by the Council on Medical Education of the American Medical Association and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed such formal 6 months of training, or (ii) prior to January 1, 1969, shall have (*a*) been graduated from high school, (*b*) completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology, and (*c*) completed 2 years of full-time experience in cytotechnology.

(c) *Standard; technician—duties.* Clinical laboratory technicians are employed in sufficient number to meet the workload demands of the laboratory and they function only under direct supervision of a clinical laboratory technologist. The factors explaining the standard are as follows:

(1) Each clinical laboratory technician performs only those procedures which require a degree of technical skill commensurate with his education, training, and limited technical skill and responsibility and a minimal exercise of independent judgment.

(2) No clinical laboratory technician performs procedures in the absence of a qualified clinical laboratory technologist, supervisor or director.

(3) A technician trainee, as defined in § 405.1311(g), performs only repetitive procedures, which require a minimal exercise of independent judgment, and he may perform such procedures only under the personal and direct supervision of a technical supervisor as defined in § 405.1314(b) or a technologist as defined in paragraph (b) of this section.

(d) *Standard; technician—qualifications.* Each clinical laboratory technician possesses a current license as a clinical laboratory technician issued by the State, if such licensing exists, and meets one of the following requirements:

(1) He is a high school graduate and has completed at least 1 year in a technician training program in a school accredited by an accrediting agency approved by the Secretary; or

(2) He is a high school graduate and has served 2 years as a technician trainee in a clinical laboratory with a director at the doctoral level as defined in § 405.1311(e) or in a laboratory approved under the supplementary medical insurance benefits program or, in a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.

(3) He is a high school graduate and has successfully completed an official military medical laboratory procedures course of at least 50 weeks' duration, and has held, at the journeyman's level, the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

(4) With respect to individuals first qualifying prior to July 1, 1971, an exception to the requirements is subparagraphs (1), (2), or (3) of this paragraph is made if the technician (i) was performing the duties of a clinical laboratory technician any time between July 1, 1961, and January 1, 1968, and (ii) has had at least 5 years of pertinent clinical laboratory experience prior to January 1, 1968 (a minimum of 30 semester hours of credit toward a bachelor's degree from an accredited institution with a chemical, physical, or a biological science as his major subject or 30 semester hours in an approved school of medical technology shall reduce the required years of experience by 2 years, with any additional hours further reducing the required years of experience at the rate of 15 hours for 1 year) and has performed the duties of a clinical laboratory technician for at least 2 years after July 1, 1966, or during the qualifying 5 years in (*a*) a clinical laboratory—with a director at the doctoral level as defined in § 405.1311(e)—of a hospital, university, health department, or medical research institution; or (*b*) in a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State; or (*c*) in a laboratory approved under the supplementary medical insurance benefits program.

(e) *Standard; personnel policies.* There are written personnel policies, practices, and procedures that adequately support sound laboratory practice. The factors explaining the standard are as follows:

(1) Current employee records are maintained and include a résumé of each employee's training, experience, duties, and date or dates of employment.

(2) Files contain evidence of adequate health supervision of employees, such as results of preemployment and periodic physical examinations, including chest X-rays, immunization records, and records of all illnesses and accidents.

(3) Work assignments are consistent with qualifications.

(4) There is a program for employee orientation.

§ 405.1316 Condition—Clinical laboratory management.

The clinical laboratory maintains records and facilities which are adequate and appropriate for the services offered.

(a) *Standard; laboratory procedure manual.* A compilation of all methods for tests which are performed in or offered by the laboratory is kept and is available in the appropriate bench area in the laboratory in a card file, notebook, methods manual, procedural textbooks or set of flow charts. Each method must be completely described, including sources of reagents, media, standards, and calibration procedures. It includes pertinent references and should be dated. A record of changes in procedures, analytical methods and recalibration is maintained, dated, and approved in writing by the director or supervisor. Each procedure is reviewed and dated by the director or supervisor at least annually.

(b) *Standard; laboratory management.* Space and facilities are adequate to properly perform the services which are performed in or offered by the laboratory. The factors explaining the standard are as follows:

(1) Workbench space is ample, well-lighted and convenient to sink, water, gas, suction and electrical outlets as necessary.

(2) Work areas are arranged so as to minimize problems in transportation and communication.

(3) The laboratory is properly ventilated.

(4) Volatile chemicals and inflammable solvents are properly stored in areas unlikely to ignite same or restricted from open flame or heat.

(5) Temperature and humidity are controlled within limits required for proper performance of tests and operation of instruments affected by these variations.

(6) Adequate fire precautions are known, posted, and observed.

(c) *Standard; collection of specimens.* No person other than a licensed physician or one otherwise authorized by law, manipulates a patient for the collection of specimens except that qualified technical personnel of the laboratory may collect blood or remove stomach contents and collect material for smears and culture under the direction or upon the written request of a licensed physician.

(d) *Standard; sterilization.* Syringes, needles, lancets or other blood letting devices capable of transmitting infection from one person to another are not reused unless they are properly sterilized prior to each use after first having been wrapped or covered in a manner which will insure that they remain sterile until the next use. Appropriate sterilization and disinfection techniques are utilized as required for tests performed on potentially contaminated material and for the protection of laboratory personnel. Disposable syringes, needles, pipettes, Petri dishes, and other disposable items are appropriately discarded immediately after use. Each sterilizing cycle contains an indicator device which assures proper sterilization, or an adequate recording thermometer is used and records kept of temperature readings.

(e) *Standard; examination and reports.* The laboratory examines specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations and reports only to those authorized by law to receive such results. The factors explaining the standard are as follows:

(1) If the patient is sent to the laboratory, a written request for the desired laboratory procedures is obtained from a person authorized by law to use findings of laboratory examinations.

(2) If only a specimen is sent, it is accompanied by a written request.

(3) If the laboratory receives reference specimens from another laboratory, it reports back to the laboratory submitting the specimens.

(f) *Standard; specimens—records.* The laboratory maintains a record indicating the daily accession of specimens each of

which is numbered or otherwise appropriately identified. The factor explaining the standard is as follows:

Records contain the following information:

(1) The laboratory number or other identification of the specimen.

(2) The name and other identification of the person from whom the specimen was taken.

(3) The name of the licensed physician or other authorized person or clinical laboratory which submitted the specimen.

(4) The date the specimen was collected by the physician or other authorized person.

(5) The date the specimen was received in the laboratory.

(6) The condition of unsatisfactory specimens when received (e.g., broken, leaked, hemolyzed or turbid, etc.).

(7) The type of test performed.

(8) The date test was performed.

(9) The result of the laboratory test or cross-reference to results and the date of reporting.

(g) *Standard; laboratory report and record.* The laboratory report is sent promptly to the licensed physician or other authorized person who requested the test and a suitable record of each test result is preserved by the laboratory for a period of at least 2 years after the date of submittal of report or for a period of time required by State law for such records, whichever is longer. The factors explaining the standards are as follows:

(1) The laboratory director is responsible for the laboratory report.

(2) Duplicate copies or a suitable record of laboratory reports are filed in the laboratory in a manner which permits ready identification and accessibility.

(3) Tissue pathology reports utilize acceptable terminology of a recognized system of disease nomenclature.

(4) The results of laboratory tests or procedures or transcripts thereof are not sent to the patient concerned except with the written consent of the physician or other authorized person who requested the test.

(5) The report forms are designed to facilitate comparison with pertinent "normal" ranges as determined by the laboratory performing the tests.

(6) A list of analytical methods employed by the laboratory and a basis for the listed "normal" range is maintained in the laboratory. The list shall be made available to any physician ordering an examination upon request.

(7) If the laboratory refers specimens to another laboratory, the laboratory receiving the specimens meets the applicable conditions under the health insurance program. Each physician ordering an examination is notified that the specimen was referred to another laboratory. Such notice must show the name and address of the laboratory to which the specimen is referred.

§ 405.1317 Quality control.

There is an adequate quality control program in effect to assure the medical reliability of laboratory data.

(a) *Standard; equipment and reagents.* Equipment and reagents are adequate to properly perform the services offered by the laboratory. The factors explaining the standard are as follows:

(1) Performance of all instruments and equipment is evaluated sufficiently often to insure proper function at all times. An effective system includes a preventive maintenance program plus an appropriate periodic inspection or test for proper operation of equipment and instruments. All automated analytical devices are recalibrated and checked according to the directions of the manufacturer.

(2) Volumetric measuring equipment is of such quality and maintained in such condition to assure accuracy and precision of results.

(3) Temperature-controlled equipment including incubators, water baths, refrigerators, and drying ovens are checked at appropriate intervals to assure accurate operation. Continuous monitoring by recording thermograph is done when appropriate.

(4) A record is maintained for each piece of equipment showing the date of inspection, record of repairs or recalibrations, and dates equipment was out of service.

(5) All solid and liquid reagents, solutions, and standards are prepared, stored, standardized, dispensed, and periodically analyzed to assure accuracy and precision of results. All reagents and solutions are labeled to indicate identity, titer, strength, or concentration. The label includes such pertinent information as hazards involved in use, recommended storage and appropriate dating indicating preparation and expiration date. Monitoring systems for reagents and materials are such as to demonstrate satisfactory performance by parallel testing with preparations of known acceptable quality.

(b) *Standard; specimen stability.* Specimens shipped to laboratories through the mail and accepted by them for analysis are sufficiently stable to assure satisfactory clinical accuracy.

(1) The methods used for the collection of specimens (including, when applicable, patient preparation prior to specimen collection), proper identification, storage, and preservation are recorded and made available to physicians using the services of the laboratory.

(2) Only specimens which are sufficiently stable to provide accurate and precise results suitable for clinical interpretation are accepted for analysis.

(c) *Standard; quality control systems—methodologies.* Provision is made for a quality control program covering all types of analysis performed by the laboratory for verification and assessment of accuracy, measurement of precision and detection of error. The factors explaining the standard are as follows:

(1) *Clinical chemistry.* Each method in clinical chemistry is rechecked at least once on each day of use. For each method, automated or manual, data is available to document the routine precision and the schedule of recalibration. At least one standard and one reference sample (control) is included with each run of unknown specimens where such standards and reference samples are available. Control charts are maintained and displayed.

(2) *Hematology.* Instruments and other devices used in hematological examination of specimens are recalibrated or retested or reinspected, as may be appropriate, each day of use. Reference materials, such as hemoglobin pools and stabilized cells, are tested at least once each day of use to insure accuracy of results. The accuracy and precision of blood cell counts and hematocrit and hemoglobin measurements are tested each day of use.

(3) *Immunohematology. Blood grouping—RH typing only.* (i) ABO grouping shall be performed by testing unknown red cells with anti-A and anti-B grouping serums licensed under Part 73, Title 42, Code of Federal Regulations, using the technique for which the serum is specifically designed to be effective. For confirmation of ABO groupings, the unknown serum shall be tested with known A^1 and B red cells.

(ii) The potency and reliability of reagents shall be checked each day of use.

(iii) The Rh_o(D) type shall be determined by testing unknown red cells with anti-Rh_o (anti-D) typing serum licensed under Part 73, Title 42, Code of Federal Regulations, or possessing equivalent potency, using the technique for which the serum is specifically designed to be effective. Anti-Rh_o' (CD), anti-Rh_o'' (DE), and anti-Rh_orh'rh'' (CDE) serums licensed pursuant to Part 73, Title 42, Code of Federal Regulations, may be used for typing of donor blood. All Rh_o negative donor and patient cells shall be tested for the Rh_o variant (D"). A control system of patient's cells suspended in his own serum or in albumin is employed when the test is performed in a protein medium.

(iv) Rh_o(D) positive and negative control tests are used for each test system employed to check the reactivity of the anti-Rh_o(D) serum each day of use. Reactivity of known cells used for antibody screening is tested each day of use with a suitable positive and negative control. The reactivity of antihuman globulin reagents (Coombs' serum) is tested each day of use and whenever a new lot of reagent is used.

(4) *Microbiology.* Chemical and biological solutions, reagents, and antisera are tested and inspected before or concurrently with use for reactivity and deterioration.

(i) *Bacteriology and mycology.* Staining materials are tested for intended reactivity by concurrent application to smears or micro-organisms with predictable staining characteristics. Each batch of medium is tested before or concurrently with use with selected organisms to confirm required growth characteristics, selectivity, enrichment, and biochemical response.

(ii) *Parasitology.* A reference collection of slides, photographs, or gross

specimens of identified parasites is available in the laboratory for appropriate comparison with diagnostic specimens. A calibrated ocular micrometer is used for determining the size of ova and parasites, if size is a critical factor.

(iii) *Virology.* Systems for the isolation of viruses and reagents for the identification of viruses is available to cover the entire range of viruses which are offered. Records are maintained which reflect the systems used and the reactions observed. In tests for the identification of viruses, controls are employed which will identify erroneous results. If serodiagnostic tests for virus diseases are performed, requirements for quality control as specified for serology are complied with.

(5) *Serology.* (i) Serologic tests on unknown specimens are run concurrently with a positive control serum of known titer or control of graded reactivity plus a negative control in order to detect variations in reactivity levels.

(ii) Each new lot of reagency is tested concurrently with one of known acceptable reactivity before the new reagent is placed in routine use.

(iii) Equipment, glassware, reagents, controls, and techniques for tests for syphilis conform to those recommended in the latest U.S. DHEW, PHS publication pertaining to the performance of tests for syphilis.[1]

(6) *Radiobioassay.* The counting equipment is checked for stability at least once on each day of use, with radioactive standards or reference sources. Reference samples with known activity and within expected levels of normal samples, are processed in replicate quarterly. For each method, records are maintained and are available to staff to document the routine precision and the recalibration schedule.

(7) *Diagnostic cytology; Histopathology; Oral pathology*—(i) *Diagnostic cytology.* The qualified physician director or supervisor rescreens for proper staining and correct interpretation at least a 10 percent random sample of gynecological smears which have been interpreted to be in one of the benign categories by cytotechnologists. All gynecological smears interpreted to be in the "suspicious" or positive categories by screeners are confirmed by the qualified physician supervisor, and the report is signed by a physician qualified in pathology or cytology. All nongynecological preparations, positive and negative, are reviewed. Nonmanual methods provide quality control similar to that provided in other nonmanual laboratory procedures. All smears are retained for not less than 2 years from date of examination.

(ii) *Histopathology and oral pathology.* All special stains are controlled for intended reactivity by use of positive slides. Stained slides are retained for intended reactivity by use of positive slides. Stained slides are retained for not less than 2 years from date of examination and blocks are retained for not less than 1 year from such date. Remnants of tissue specimens are retained in a fixative solution until those portions submitted for microscopy have been examined and a diagnosis made by a pathologist.

[1] Obtainable from U.S. Government Printing Office.

[FR Doc.72-2298 Filed 2-15-72;8:53 am]

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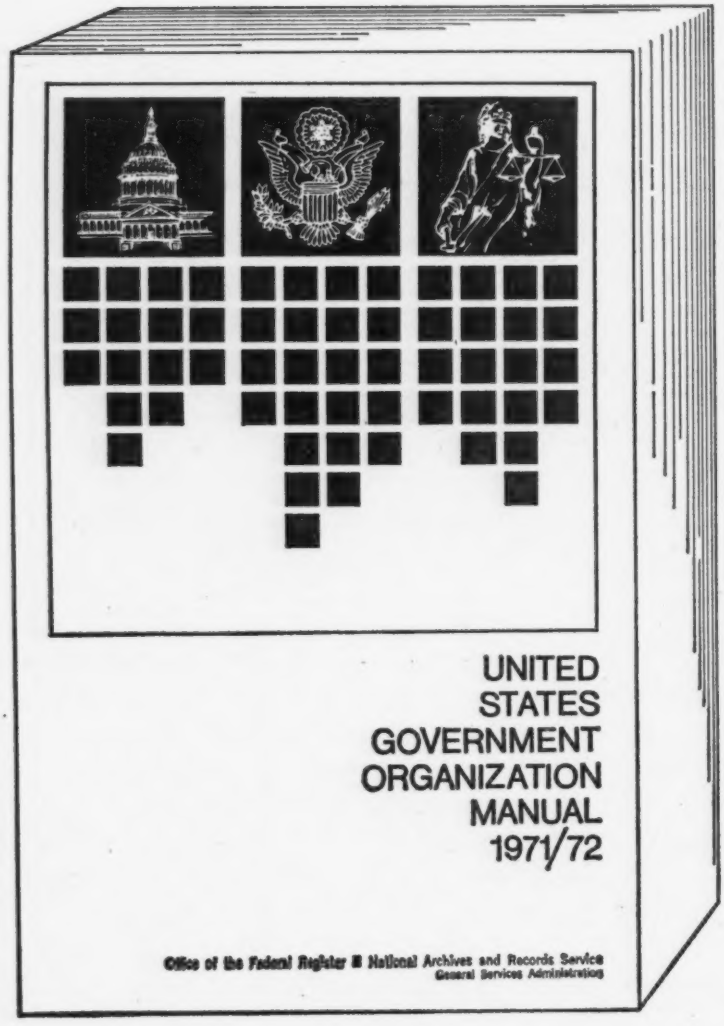

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